REMARKS

In the Office action, the specification was objected to because of informalities therein. In response to this objection, a replacement specification is filed herewith, in which no new matter is added. Claims 1–17 are deleted without prejudice. Claims 18 and 19 have been amended to increase clarity. New claims 21-31 have been added. Support for the new claims can be found throughout the specification as filed. Particular support for new Claims 21-25 can be found at page 4, line 27 to page 6, line 5 of the specification as originally filed. Support for Claims 26-29 can be found at page 5, lines 11-18 of the specification as originally filed. Finally, support for new Claims 30-31 can be found at page 1, lines 10-13, page 2, lines 2-3 and page 4, lines 4, 8 and 22. Thus, no new matter has been added. In view of the amendments and comments presented herein, reconsideration and withdrawal of the claim rejections are respectfully requested.

Objection and Rejections under 35 U.S.C. §112, first paragraph

The Examiner objected to the specification and rejected claims 1-8 and 11-20 under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate written description and failing to provide an enabling disclosure. More particularly, the claims were rejected for failing to provide evidence that the claimed biological materials (i.e. anti-NC1 antibodies) are known and readily available to the public.

The claimed anti-NC1 monoclonal antibody has been commercially manufactured and sold by a Japan-based company, Cosmo Bio Co Ltd., since April, 2002. Three printed documents, a catalog of Cosmo Bio Co Ltd, a product listing of Cosmo Bio Co Ltd., and a correspondence between Collagen Research Center (a company that an inventor, Dr. Yokoyama owns) and Cosmo Bio Co Ltd. are provided in the accompanying IDS. These printed documents evidence the commercial availability of the antibodies.

According to MPEP § 2404.01, there are many factors that may be used as indicia that a biological material is known and readily available to the public. Relevant factors include commercial availability and references to the biological material in printed publications. The Office will accept commercial availability as evidence that a biological material is known and readily available when the evidence is clear and convincing that the public has access to the material. Here, clear evidence is present in the form of the printed documents. Accordingly, the

claimed materials, namely the anti-NC1 antibodies are known and readily accessible to the public through commercial sale. Therefore, as to current pending claims 18-31, the claims meet the written description and enablement provision of 35 U.S.C. § 112, first paragraph. Applicants respectively request withdrawal of these rejections to claims.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1-9 and 11-20 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claims 1-17 are deleted and therefore rejections to these claims are now moot. As to claims 18-20, more particularly, the Examiner commented that the acronym "NC1" should not be used until fully defined as its first occurrence in the independent claim such as by – noncollagenous domain of collagen (NC1). The independent claims 18 and 21 now cite the full definition of NC1.

As to claim 18, the Examiner also commented that it is unclear if blood or serum (or plasma) is being treated. In responding to this comment, the language "sera" is deleted to further specify blood is being treated.

As to claim 19, the Examiner commented that "the" internal circulation in the claim lacks antecedent basis. The word "the" has been substituted with "an" so as to obviate this rejection

In light of foregoing amendments, Applicants respectively submit that claims 18-29 are now in compliance with the requirement for definiteness under 35. U.S.C. 112, second paragraph, therefore request withdrawal of rejections to the claims.

Rejections under 35 U.S.C. §102

Claims 3 and 5-8 were rejected under 35. U.S.C. 102(b) as being allegedly anticipated by Borza et al. (J. Biol. Chem. 276: 28532, 2001) and also by Johansson et al. (J. Biol. Chem. 267: 24533, 1992). Claim 6 was rejected under 35. U.S.C. 102(b) as being allegedly anticipated by Oftshun et al (US 5871649) in light of Sugihara et al. (J. Pathol. 178: 352, 1996). Claim 9 is rejected by Kitchell et al. (US 5656298) under 35. U.S.C. 102(b) and also rejected by Chambers et al. (US 6696281) under 35. U.S.C. 102(e)(2). Claims 3 and 5-9 are deleted, therefore rejections to these claims are now moot.

The rejections did not apply to previously pending Claims 18-20. For similar reasons, none of the rejections apply to new Claims 21-31.

Further Discussion of Amendments

In view of the amendments, the currently pending claims generally relate to an apparatus and methods for using or manufacturing the anti-NC1 antibody. For example, claims 18-20 recite, among other things, a method or apparatus in relation to removing the antibody and/or NC1 from blood. The newly added claims 21-31 generally direct to a method of identifying nephritis by using anti-NC1 antibodies. Claims 30-31 relate specifically to the early stage of nephritis, which may include the conditions before granular deposition of IgA into the renal glomerular basement membrane (GBM) or formation of glomerular crescent (See, for example, Abstract, and Specification at page 1, lines 10-13, page 2, lines 2-3 and page 4, line 4, lines 8 and 22 from English-translation of the instant application).

Applicants wish to note that the three documents submitted in the accompanying IDS may be considered to disclose antibodies within the scope of those recited in the presently pending claims, these claims are directed a method or apparatus of using or removing the antibody, which are believed to be patentable over these documents. The catalog of Cosmo Bio Co Ltd shows the name of antibody (i.e. K35MONO) and its antigen (i.e. anti collagen IV NC1 domain), however, no specific use of the antibody has been disclosed therein. In addition, the letter from the Inventor to Cosmo Bio Co Ltd. cited the K35 NC1-specific antibodies, however, only the name of antibodies and general information related to production and storage conditions are disclosed therein. The letter also described the product of K35 NC1 which is concentrated proteins of K35 NC1. K35 NC1 is the specific antigen of the anti-NC1 antibody. While the letter states that the K35 NC1 product can be used to prepare or induce nephritis model [in an experimental system], it does not disclose that K35 NC1 can be used to identify the presence of nephritis, as claimed in Claims 21-31, much less the early stage nephritis specifically claimed in Claims 30-31.

In addition, claimed matters in claims 18-20 have also not been disclosed in the prior art. Therefore, claims 18-20 are also patentable even in the view of the prior art. Accordingly, Applicants respectively submit claims 18-31 as patentable over the art of record.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' foregoing Amendments and Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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